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Our Case No.: 11202/5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Todd Bucciarelli, et al.

Examiner: Unknown

Serial No.: Unknown

Group Art Unit No.:

Filing Date: August 22, 2003

For: METHODS AND COMPOSITIONS
FOR INCREASING PROTEIN
YIELD FROM A CELL CULTURE

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed below and on the attached Form PTO-1449 be considered by the Examiner and made of record. This application is a divisional application of U.S. Application Serial No. 09/935,194, filed August 21, 2001 and is relied upon for an earlier filing dated under 35 U.S.C. § 120. The references listed below and on PTO Form 1449 were cited by or submitted to the Office in connection with prosecution of U.S. Application Serial No. 09/935,194, filed August 21, 2001, and therefore, pursuant to 37 C.F.R. § 1.98(d), copies of the listed documents are not enclosed.

The references now cited are the following:

U.S. Patent Documents:

US 6,274,341 Aug 14, 2001 Bailey et al.
US 5,891,718 April 6, 1999 Hobart et al.

Foreign Patent Documents:

WO 94/04672 Mar 3, 1994 PCT

Other Art:

Serrano et al., "A new regulatory motif in cell-cycle control causing specific inhibition of cyclin D/CDK4", Nature, vol 366, pages 704-707 (December 16, 1993).

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Serrano et al., "Role of the INK4a Locus in Tumor Suppression and Cell Mortality", *Cell*, vol 85, pages 27-37 (April 5, 1996).

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Toyoshima et al., "p27, a Novel Inhibitor of G1 Cyclin-Cdk Protein Kinase Activity, Is Related to p21", *Cell*, vol 78, pages 67-74 (July 15, 1994).

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Harper et al., "The p21 Cdk-Interacting Protein Cip 1 Is a Potent Inhibitor of G1 Cyclin-Dependent Kinases", *Cell*, vol 75, pages 805-816 (November 19, 1993).

Driscoll et al., "Cyclin D1 antisense RNA destabilizes pRb and retards lung cancer cell growth", *Am. J. Physiol.*, vol 273, pages L941-L949 (1997).

Buchkovich et al., "The Retinoblastoma Protein is Phosphorylated during Specific Phases of the Cell Cycle", *Cell*, vol 58, pages 1097-1105 (September 22, 1989).

Deng et al., "Mice Lacking p21^{cip1/WAF1} Undergo Normal Development, but Are Defective in G1 Checkpoint Control", *Cell*, vol 82, pages 675-684 (August 25, 1995).

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Hengst et al., "Translational Control of p27^{Kip1} Accumulation During the Cell Cycle", *Science*, vol 271, pages 1861-1864 (29 March 1996).

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Mazur et al., *Higher Productivity of Growth-Arrested Chinese Hamster Ovary Cells Expressing the Cyclin-Dependent Kinase Inhibitor p27*. *Biotechnol. Prog.* 1998, 14, pp 705-13

Mazur et al., *A Novel Autoregulated Proliferation-Controlled Production Process Using Recombinant CHO Cells*. *Biotechnology and Bioengineering*, vol. 65, no. 2, pp. 144-50 October 20, 1999

Geserick et al., *Enhanced Productivity During Controlled Proliferation of BHK Cells in Continuously Perfused Bioreactors*. Biotechnology and Bioengineering, vol. 69, no. 3, pp. 266-74, August 5, 2000

Taniguchi et al., *Induction of the p16^{INK4a} Senescence Gene as a New Therapeutic Strategy for the Treatment of Rheumatoid Arthritis*. Nature Medicine, vol. 5, no. 7, pp. 760-67 July 1999.

In accordance with 37 C.F.R. § 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This Information Disclosure Statement is being filed prior to the receipt of the first Official Action reflecting an examination on the merits and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these material, the Commissioner is hereby authorized to deduct said fees from Brinks Hofer Gilson & Lione Deposit Account No. 23-1925. A duplicate copy of this document is enclosed.

Applicant(s) respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

Augent 22, 2003

John Murray
John Murray
Registration No. 44,251
Attorney for Applicant(s)

BRINKS HOFER GILSON & LIONE

P.O. Box 10395
Chicago, IL 60610
(312) 321-4200

FORM PTO-1449		SERIAL NO. Unknown	CASE NO. 11202/5
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		FILING DATE August 22, 2003	GROUP ART UNIT Not assigned
(use several sheets if necessary)		APPLICANT(S): Bucciarelli, Todd et al.	

REFERENCE DESIGNATION **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
A1	US 6,274,341	Aug 14, 2001	Bailey et al.		
A2	US 5,891,718	April 6, 1999	Hobart et al.		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES NO
A3	WO 94/04672	Mar 3, 1994	PCT		

EXAMINER INITIAL	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)	
A4	Serrano et al., "A new regulatory motif in cell-cycle control causing specific inhibition of cyclin D/CDK4", Nature, vol 366, pages 704-707 (December 16, 1993).	
A5	Rivard et al., "Abrogation of p27 ^{Kip1} by cDNA Antisense Suppresses Quiescence (G ₀ State) in Fibroblasts", Journal of Biological Chemistry, vol 271 no 31, pages 18337-18341 (August 2, 1996).	
A6	Weber et al., "An SV40 "Enhancer Trap" Incorporates Exogenous Enhancers or Generates Enhancers from Its Own Sequences", Cell, vol 36, pages 983-992 (April 1984).	
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A8	Kato et al., "Cyclic AMP-Induced G1 Phase Arrest Mediated by an Inhibitor (p27 ^{Kip1}) of Cyclin-Dependent Kinase 4 Activation", Cell, vol 79, pages 487-496 (November 4, 1994).	
A9	Coats et al., "Requirement of p27 ^{Kip1} for Restriction Point Control of the Fibroblast Cell Cycle", Science, vol 272, pages 877-880 (May 10, 1996).	
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A12	Matsuoka et al., "p57 ^{Kip2} , a structurally distinct member of the p21 ^{Cip1} Cdk inhibitor family, is a candidate tumor suppressor gene", Genes & Development, 9, pages 650-662 (1995).	
A13	Cristofalo et al., "Enzyme Activity during the Growth and Aging of Human Cells <i>in Vitro</i> ", Journal of Cellular Physiology, 69, pages 263-272 (1967).	
A14	Goldstein et al., "Studies on the Molecular-Genetic Basis of Replicative Senescence in Werner Syndrome and Normal Fibroblasts", Experimental Gerontology, vol 24, 1989, pages 461-468.	
A15	Ewen et al., "Functional Interactions of Retinoblastoma Protein with Mammalian D-type Cyclins", Cell, vol 73, pages 487-497 (May 7, 1993).	

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A16	Polyak et al., "Cloning of p27 ^{KIP1} , a Cyclin-Dependent Kinase Inhibitor and a Potential Mediator of Extracellular Antimitogenic Signals", Cell, vol 78, pages 59-66 (July 15, 1994).	
A17	Levenson et al., "Internal Ribosomal Entry Site-Containing Retroviral Vectors with Green Fluorescent Protein and Drug Resistance Markers", Human Gene Therapy, 9:1233-1236 (May 20, 1998).	
A18	Brenner et al., "Increased p16 expression with first senescence arrest in human mammary epithelial cells and extended growth capacity with p16 inactivation", Oncogene, 17, 199-205 (1998).	
A19	Chang et al., "Role of p53 and p21 ^{WAF1/CIP1/Sdi1} in senescence-like terminal proliferation arrest induced in human tumor cells by chemotherapeutic drugs", Oncogene, 18, 4808-4818 (1999).	
A20	Fabbrizio et al., "Inhibition of mammalian cell proliferation by genetically selected peptide aptamers that functionally antagonize E2F activity", Oncogene, 18, 4357-4363 (1999).	
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A22	Campisi, "Cancer, Aging and Cellular Senescence", In Vivo, 14:183-188 (2000).	
A23	Dimri et al., "A biomarker that identifies senescent human cells in culture and in aging skin <i>in vivo</i> ", Proc. Natl. Acad. Sci. USA, vol 92, pages 9363-9367 (September 1995).	
A24	Chang et al., "Effects of p21 ^{WAF1/CIP1/Sdi1} on cellular gene expression: Implications for carcinogenesis, senescence, and age-related diseases", PNAS, vol 97 no. 8, pages 4291-4296 (April 11, 2000).	
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A30	Gray et al., "Exploiting Chemical Libraries, Structure, and Genomics in the Search for Kinase Inhibitors", Science, vol 281, pages 533-538 (24 July 1998).	
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A33	Dimri et al., "Regulation of a Senescence Checkpoint Response by the E2F1 Transcription Factor and p14 ^{ARF} Tumor Suppressor", Molecular and Cellular Biology, vol 20, no 1, pages 273-285 (January 2000).	

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A56	Geserick et al., <i>Enhanced Productivity During Controlled Proliferation of BHK Cells in Continuously Perfused Bioreactors</i> . Biotechnology and Bioengineering, vol. 69, no. 3, pp. 266-74, August 5, 2000	
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